[ECF No. 18]

THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE SUBPOENA TO FUJIFILM IRVINE SCIENTIFIC	**Civil No. 24-8830 (CPO/EAP)**

MEMORANDUM ORDER

This matter having come before the Court upon Non-Party FujiFilm Irvine Scientific Inc.'s ("FISI") Motion to Quash Related to a Subpoena from Another District, ECF No. 18; and the Court having conducted a motion hearing on the record on September 13, 2024; and the Court noting the following appearances: **Liza Walsh, Esquire; Marc D. Haefner, Esquire**; **Michael D. Hatcher, Esquire**; **Wendy Whiteford, Esquire**; **C. Nichole Gifford, Esquire**; **Steven Tang, Esquire; Chelsea Ostrer, Esquire; Gourdin W. Sirles, Esquire; and Siegmund Gutman, Esquire**, appearing on behalf of Plaintiff Amgen Inc.; **Rebekah Conroy, Esquire and Jennifer C. Tempesta, Esq.**, appearing on behalf of non-party FISI; and **James S. Richter, Esquire**, appearing on behalf of Defendant Celltrion, Inc. For the reasons stated on the record, FISI's Motion is **GRANTED IN PART AND DENIED IN PART**.

BACKGROUND

On May 28, 2024, Amgen, Inc. ("Amgen") filed a Complaint for patent infringement against Celltrion, Inc. ("Celltrion") regarding two of its products: (1) Prolia, a drug prescribed to treat patients with a high risk of bone fracture; and (2) XGEVA, a drug prescribed to prevent skeletal-related events in cancer patients whose cancer has spread to the bone. *Amgen v. Celltrion*, Civil Action No. 24-6497 (CPO)(EAP), ECF No. 1 (Compl.) ¶ 2. The patents-in-suit cover denosumab (the active ingredient in Prolia and XGEVA) and the methods of manufacturing denosumab and denosumab products. *Id.*

¶ 3. According to the Complaint, Celltrion submitted to the Food and Drug Administration ("FDA") a Biologics License Application ("BLA") seeking approval to manufacture and sell biosimilar versions of Prolia and XGEVA. *Id.* ¶ 4. Amgen claims that it sought certain information from Celltrion to determine whether it would infringe certain of Amgen's patents, but Celltrion refused to provide the requested information. *Id.* As such, Amgen filed the present Complaint for a declaration of infringement under the Biologics Price Competition and Innovation Act ("BPCIA"), 42 U.S.C. § 262(*l*)(9)(C). *Id.* ¶ 6.

During the BPCIA's information exchange, Amgen learned that certain information regarding the manufacture of Celltrion's biosimilars, including information regarding the composition of the accused products' cell culture media used in manufacture, was not included in the provided documentation. When Amgen inquired about the missing information, Celltrion indicated that it did not possess the information because it purchases its cell culture media from non-party FISI, and it directed Amgen to obtain documentation regarding the composition of the cell culture media directly from FISI. *See* ECF No. 7-14, Declaration of Gourdin Sirles ("Sirles Decl.") at Ex. 1.

Accordingly, Amgen served on FISI a subpoena for twenty-nine categories of documents (the "Subpoena") seeking information regarding FISI's cell culture media. *See* ECF No. 7-3, Joint Stipulation, Ex. A (Subpoena). Of those categories, twenty-five are in dispute: (a) interrogatories regarding the full composition and concentrations of FISI's cell culture media (Request Nos. 1-4); (b) information regarding communications between FISI and Celltrion (Request Nos. 15-20, 23-26); and (c) requests for which FISI has represented either that it has already produced responsive documents or it does not have any responsive documents (Request Nos. 5-12, 21-22.).

STANDARD OF REVIEW

When a party serves a subpoena under Federal Rule of Civil Procedure 45, the information and documents sought must fall within the scope of proper discovery under Rule 26(b)(1). *In re Novo*

Nordisk Sec. Litig., 530 F. Supp. 3d 495, 501 (D.N.J. 2021). Rule 26 provides,

> [p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit.

Fed. R. Civ. P. 26(b)(1). "'Rule 26 [clearly] establishes a liberal discovery policy' and '[t]he federal courts have . . . long permitted broad and liberal discovery." *Khal Anshei Tallymawr Inc. v. Twp. of Toms River*, Nos. 21-2716, 23-3239, 2024 WL 3728069, at *3 (D.N.J. Aug. 8, 2024) (quotations omitted). However, the scope of discovery "is not unlimited . . . and should not serve as a fishing expedition." *Burgess v. Galloway*, No. 20-6744, 2021 WL 2661290, at *2 (D.N.J. Jan. 28, 2021) (quotation omitted).

Federal Rule of Civil Procedure 45(d)(3)(A) provides for when a court must quash a subpoena:

> On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
> (i) fails to allow a reasonable time to comply;
> (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
> (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
> (iv) subjects a person to undue burden.

Fed. R. Civ. P. 45(d)(3)(A)(i–iv).

When proceeding under Rule 45(d)(3)(A)(iv), "[t]he party seeking to quash the subpoena bears the burden of demonstrating that the requirements of Rule 45 are satisfied." *Strike 3 Holdings, LLC v. Doe,* No. 18-16593, 2019 WL 475360, at *3 (D.N.J. Sept. 30, 2019) (quoting *Malibu Media, LLC v. John Does 1-15*, No. 12-2077, 2012 WL 3089383, at *5 (E.D. Pa. July 30, 2012) (further quotations omitted)). This burden has been described as "heavy." *Id.* Indeed, an undue burden requires a "clearly defined and serious injury." *Plastic the Movie Ltd v. John Doe Subscriber Assigned IP Address 23.0.10.163*, 15-2446, 2015 WL 4715528, at *2 (D.N.J. Aug. 7, 2015). The

movant must also show that the subpoena is "unreasonable and oppressive." *Burgess*, 2021 WL 2661290, at *3.

Once the movant meets this heavy burden, a court must balance the subpoenaing party's interest in disclosure against the subpoenaed party's interest in non-disclosure to determine whether the burden on the nonparty is undue. *In re Domestic Drywall Antitrust Litig.*, 300 F.R.D. 234, 239 (E.D. Pa. 2014). The balancing test requires the court to weigh (1) the relevance; (2) need; (3) confidentiality of the requested materials; and (4) the harm that compliance would cause the subpoenaed nonparty. *Id.* at 239.

In light of these standards, and for the reasons stated on the record,

IT IS this **13th** day of **September 2024**, **ORDERED** as follows:

1. **Requests for Production Nos. 1 to 4:** The Motion to Quash as to Requests for Production Nos. 1-4 is **GRANTED IN PART and DENIED IN PART**, as follows:

    a. No later than **September 20, 2024**, counsel for Amgen, Celltrion, and FISI shall meet and confer and provide a proposed expanded confidentiality order that will govern FISI's production of documents regarding its cell culture media. The confidentiality order shall include the following restrictions:

        i. The only Amgen in-house counsel who may access or review the documents will be the four Amgen attorneys currently admitted *pro hoc vice* in this action (Wendy Whiteford, C. Nichole Gifford, Steven Tang, and James High);

        ii. Attorneys Whiteford, Gifford, Tang, and High shall not be involved in Amgen's competitive decision-making for cell culture media;

        iii. Celltrion shall be bound by the same restrictions with respect to FISI's confidential information; and

        iv. Amgen and Celltrion shall agree to be subject to corporate liability for any breach of the confidentiality order.

    b. Within **ten (10) days** from the date that the Court signs the confidentiality order, FISI shall produce to Amgen responses to Requests for Production Nos. 1–4.

2. **Requests for Production Nos. 5 to 8:** The Motion to Quash as to Requests for Production Nos. 5-8 is **GRANTED IN PART and DENIED IN PART**. No later than **September 20, 2024**, FISI must provide either an affidavit or a certified letter indicating that no responsive documents exist.

3. **Requests for Production Nos. 9 to 12:** The Motion to Quash as to Requests for Production Nos. 9-12 is **GRANTED**. The Certificates of Analysis previously produced by FISI satisfy FISI's obligation with respect to these Requests.

4. **Requests for Production No. 15 to 20 and 23 to 25**: The Motion to Quash as to Requests for Production Nos. 15-20 and 23-25 is **GRANTED**. Counsel for Amgen and Celltrion should meet and confer, and Celltrion should produce all documents responsive to these requests no later than **September 20, 2024**. If Celltrion does not possess certain responsive documents, Amgen may, upon full review of the documents received from Celltrion, renew its requests to FISI.

5. **Request for Production No. 21 to 22:** The Motion to Quash as to Requests for Production Nos. 21 and 22 is **GRANTED IN PART and DENIED IN PART**. No later than **September 20, 2024**, FISI must certify that no responsive documents exist.

6. **Request for Production No. 26:** The Court **RESERVES** a ruling on the Motion to Quash pending Amgen's review of the information produced by Celltrion in response to Request for Production Nos. 15-20 and 23-25.

THE FAILURE OF A PARTY OR ATTORNEY TO OBEY THIS ORDER MAY RESULT IN IMPOSITION OF SANCTIONS UNDER FED. R. CIV. P. 16(f).

s/Elizabeth A. Pascal
ELIZABETH A. PASCAL
United States Magistrate Judge

cc: Hon. Christine P. O'Hearn, U.S.D.J.